Notice of Allowability	Application No.	Applicant(s)	
	10/531,305	EBINUMA, HIROYUKI	
	Examiner	Art Unit	
	Lisa J. Hobbs	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to _____.

2. ☒ The allowed claim(s) is/are *1, 3-5 and 7-9*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date See Continuation Sheet
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20070820* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Continuation of Attachment(s) 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 20050413; 20050531; 20050708; 20060616.

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d) on April 13, 2005, as part of this National Stage application, which papers have been placed of record in the file.

Claim Status

Claims 1-9 are pending in the instant application. No claims have been cancelled or amended in preliminary amendments. Claims 2 and 6 are cancelled as part of the Examiner's Amendment (below). Claim 9 is allowed. Claims 1, 3-5, and 7-8 are allowed as amended in the Examiner's Amendment (below).

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jacob Doughty on August 14, 2007.

The application has been amended as follows:

A. Please substitute the following claims for the claims currently in the application.

1. (Currently Amended): A method of defructosylating a fructosylated peptide or protein, comprising reacting the peptide or protein with an enzyme that is extracted from a plant of the genus Zingiber and exhibits defructosylation action.

2. (Cancelled)

3. (Currently Amended): The defructosylation method according to claim 1, wherein the fructosylated peptide comprises the amino acid sequence of any of SEQ ID NOs: 1 to 5.

4. (Currently Amended): The defructosylation method according to claim 1 or claim 3, wherein the fructosylated protein is hemoglobin A1c.

5. (Currently Amended): An enzyme that exhibits defructosylation action on a fructosylated peptide or protein and is extracted from a plant of the genus Zingiber.

6. (Cancelled)

7. (Currently Amended): The enzyme according to claim 5, wherein the enzyme has the following physical and chemical characteristics a) to h):
a) Action: in the presence of oxygen, acting on a fructosyl valine or fructosyl peptide wherein the fructosyl peptides may be selected from peptides comprising the amino acid sequences of SEQ ID NOs: 1 to 5, and catalyzing at least a reaction which produces corresponding valine or non-fructosyl peptide, glucosone, and hydrogen peroxide;
b) Optimum pH: 8.0 to 9.0;
c) Range of stable pH: pH 6.0 to 7.0;
d) Km value for fructosyl valyl histidine: 1.2 mM;
e) Range of optimum temperature: 60°C. or more;
f) Temperature stability: 80% or more of the enzyme activity remains after heat-treatment for 15 minutes at 50°C.; and
g) Molecular weight: approximately 27 kDa by gel filtration.

8. (Currently Amended): A method for measuring a fructosylated peptide or protein, comprising measuring at least one reaction product produced through the defructosylation method according to claim 1 or claim 3.

9. (Original): The method for measuring a fructosylated-peptide or protein according to claim 8, wherein the reaction product produced through the defructosylation method is hydrogen peroxide, glucosone, or a defructosyl peptide.

B. Please substitute the following title for the title currently in the application.

"Fructosyl Peptide Oxidase and Utilization Thereof"

The following is an examiner's statement of reasons for allowance:

After a thorough search of the prior art, it was determined that a fructosyl peptide oxidase, described as defructosylating enzyme, isolated from Zingiber (ginger) plants was not previously known. As described on page 7 of the specification, " 'defructosylation' refers to removing a fructosyl moiety from a fructosyl amino acid or fructosyl peptide, i.e., through, for example, oxidation decomposition, thereby generating non-fructosylated amino acid or peptide", which does not encompass activity such as peptide cleavage activity. The specification continues, that the instant defructosylation enzyme is "preferably an enzyme which produces a glucosone and a defructosylated peptide or protein from a fructosyl peptide or protein."

As well, it was determined that claims to fructosyl peptide oxidase enzymes and uses thereof from any and all plants, or any and all members of the Zingiberaceae family, were beyond the scope of the description presented in the specification. A brief search revealed that there are more than 1,000 species in the Zingiberaceae family comprised within 47 genera.

However, since the discovery of a plant fructosyl peptide oxidase was unusual, as illustrated by US 2006/0172367 A1 which states that "[f]ructosyl amino acid oxidase, one of the oxidoreductases, has generally been purified from microorganisms" (col. 1) followed by a list of documents outlining fructosyl amino acid oxidases from Corynebacterium, Aspergillus, Gibberella, and Fusarium (cols. 1-2), claims limited to members of the Zingiber family, examples of which are described on page 7 of the specification and in the examples, would be appropriate. Additionally, Wu [(2003) Arch. Biochem. Biophys. 419(1): 16-24] states in a review of the subject that the peptide amino acid oxidase enzyme, also called amadoriase, is not known from higher organisms (p.19).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Monday through Thursday, 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lisa J. Hobbs
Primary Examiner
Art Unit 1657

ljh